

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Patnaik et al

Examiner: Unassigned

Serial No. Unassigned

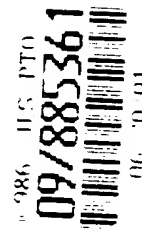
Group Art Unit: Unassigned

Filed: Herewith

Docket No. 498-128 CPA/CON

Dated: June 20, 2001

For: ePTFE SMALL CALIBER  
VASCULAR GRAFTS WITH  
SIGNIFICANT PATENCY  
ENHANCEMENT VIA A  
SURFACE COATING WHICH  
CONTAINS COVALENTLY  
BONDED HEPARIN



Date June 20, 2001 Label No. ET340223534US  
I hereby certify that on the date indicated above I  
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Barbara Kemmlein  
Name (Print)

(Signature)

Commissioner for Patents  
Washington, DC 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In fulfillment of the requirements of candor and good faith set forth in 37 C.F.R. §1.56,  
Applicant submits herewith the following Information Disclosure Statement in accordance with  
the provisions of 37 C.F.R. §1.97 and 1.98.

As this Information Disclosure Statement is being filed with the application and before  
the issuance of the first Office Action, no fee is deemed necessary.

## I. U.S. PATENTS

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
4,229,838 to Mano	Vascular Prosthesis Having A Composite Structure	October 28, 1980
4,521,564 to Solomon et al.	Covalent Bonded Antithrombogenic Polyurethane Material	June 4, 1985
4,600,652 to Solomon et al.	Permanently Bonded Antithrombogenic Polyurethane Surface	July 15, 1986
4,331,697 to Kudo et al.	Novel Heparin Derivative, Method For Production Thereof, and Method For Rendering Biomedical Materials Antithrombotic by Use of the Novel Heparin Derivative	May 25, 1982
4,613,517 to Williams et al.	Heparinization of Plasma Treated Surfaces	September 23, 1986
4,642,242 to Solomon et al.	Permanently Bonded Antithrombogenic Polyurethane Surface	February 10, 1987
4,678,660 to McGary et al.	Thermoplastic Polyurethane Anticoagulant Alloy Coating	July 7, 1987
4,713,402 to Solomon	Process For Preparing Antithrombogenic/ Antibiotic Polymeric Plastic Materials	December 15, 1987
4,720,512 to Hu et al.	Polymeric Articles Having Enhanced Antithrombogenic Activity	January 19, 1988
4,786,556 to Hu et al.	Polymeric Articles Having Enhanced Antithrombogenic Activity	November 22, 1988
4,973,493 to Guire	Method of Improving the Biocompatibility of Solid Surfaces	November 27, 1990
4,979,959 to Guire	Biocompatible Coating For Solid Surfaces	December 25, 1990

5,028,597 to Kodama et al.	Antithrombogenic Materials	July 2, 1991
5,061,777 to Yoda et al.	Thromboresistant Polyetherurethane Compounds and Process For Its Production	October 29, 1991
5,077,352 to Elton	Flexible Lubricious Organic Coatings	December 31, 1991
5,077,372 to Hu et al.	Amine Rich Fluorinated Polyurethaneureas and Their Use in a Method to Immobilize an Antithrombogenic Agent on a Device Surface	December 31, 1991
5,132,108 to Narayanan et al.	Radiofrequency Plasma Treated Polymeric Surfaces Having Immobilized Anti- Thrombogenic Agents	July 21, 1992
5,134,192 to Feijen et al.	Process For Activating a Polymer Surface For Covalent Bonding For Subsequent Coating With Heparin or the Like	July 28, 1992
5,171,264 to Merrill	Immobilized Polyethylene Oxide Star Molecules for Bioapplications	December 15, 1992
5,244,654 to Narayanan	Radiofrequency Plasma Biocompatibility Treatment of Inside Surfaces of Medical Tubing and the Like	September 14, 1993
5,258,041 to Guire et al.	Method of Biomolecule Attachment to Hydrophobic Surfaces	November 2, 1993
5,336,518 to Narayanan et al.	Treatment of Metallic Surfaces Using Radiofrequency Plasma Deposition and Chemical Attachment of Bioactive Agents	August 9, 1994
5,409,696 to Narayanan et al.	Radiofrequency Plasma Treated Polymeric Surfaces Having Immobilized Anti- Thrombogenic Agents	April 25, 1995
5,436,291 to Levy et al.	Calcification-Resistant Synthetic Biomaterials	July 25, 1995

5,451,424 to  
Solomon et al.

Anti-Infective and Antithrombogenic  
Medical Articles and Method For Their  
Preparation

September 19, 1995

## II. FOREIGN APPLICATIONS

<u>Country/ Publication No.</u>	<u>Title</u>	<u>Publication Date</u>
PCT WO 89/05616	Biocompatible Coatings	June 29, 1989
PCT WO 90/00343	Multifunctional Thrombo-Resistant Coatings and Methods of Manufacture	January 25, 1990
PCT WO 91/15952	Gas Permeable Thrombo-Resistant Coatings and Methods of Manufacture	October 31, 1991
PCT WO 91/19521	Method of Modifying the Properties of a Substrate Surface by Covalent Bonding of a Compound to the Surface, and Membrane Modified According to This Method	December 26, 1991
PCT WO 94/10938	Anticoagulant Plasma Polymer-Modified Substrate	May 26, 1994
EPO 0 263 184 A1	Immobilized Physiologically Active Material	April 13, 1988
* EPO 0 404 515 A2	Amine Rich Fluorinated Polyurethaneureas and Their Use in a Method to Immobilize an Antithrombogenic Agent on a Device Surface	December 27, 1990
EPO 0 519 087 A1	Method For Pretreating the Surface of a Medical Device	December 23, 1992
EPO 0 790 042 A2	Artificial Blood Vessel	August 20, 1997

### III. NON-PATENT DOCUMENTS

1. Heparin Immobilization by Surface Amplification, Ai-Zhi Piao, Harvey A. Jacobs, Ki Dong Park, and Sung Wan Kim, ASAIO Journal 1992, Slide Forum 26, Biomaterials/Surface Treatments, ppg. M638-M643
2. Heparin Immobilization onto Segmented Polyurethaneurea Surfaces - Effect of Hydrophilic Spacers, Journal of Biomedical Materials Research, Vol. 22, 977-992 (1988).
3. SPUU-PEO-Heparin Graft Copolymer Surfaces, Patency and Platelet Deposition on Canine Small Diameter Arterial Grafts.
4. Synthesis and Characterization of SPUU-PEO-Heparin Graft Copolymers, J. Polymer Science, Part A: Polymer Chemistry, Vol. 29, 1725-1737 (1991).
5. PEO-Modified Surfaces-In Vitro, Ex Vivo, and In Vivo Blood Compatibility. Poly (Ethylene Glycol) Chemistry; Biotechnical and Biomedical Applications. (1992).
6. In Vivo Nonthrombogenicity of Heparin Immobilized Polymer Surfaces.

Copies of each of these references have been previously been submitted in an Information Disclosure Statement submitted in the related application, U.S. Serial No. 08/713,800. Copies of references not previously submitted are submitted herewith and are denoted by an asterisk (\*). Accordingly, the Examiner is invited to refer to such prior applications for copies of each of the references.

All of the references listed above are also listed on Applicant's Substitute Form PTO-1449 which is attached to this Information Disclosure Statement for the convenience of the Examiner.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Daniel A. Seola, Jr.', written over the printed name.

Daniel A. Seola, Jr.  
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Attorney for Applicants

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